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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,421	12/09/2003	Mohan Krishnan	279.650US1	3925

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,421	KRISHNAN ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-20 and 24* is/are pending in the application.

4a) Of the above claim(s) *2-4, 8, and 19-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,9-18 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 2–4, 8, and 19–23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08 April 2005.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 5, 7, 9, 10, 17, 18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon, U.S. Patent 5,861,023 and in view of McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572.

Regarding claims 1 and 17, Vachon discloses a lead body extending from a proximal end to a distal end; and an electrode coupled to a lead body (Fig. 1); a lead body and an electrode

each have an outer surface adapted to passively prevent and means for passively preventing formation of clots on outer surfaces (column 1, lines 9–12; column 4, lines 13–21). Vachon does not disclose an outer surface of a lead body is adapted/means for passively preventing clots on a lead body includes forming a lead body such that a pseudo-intimal layer is formed on an outer surface when exposed to a bloodstream. However, McAuslan discloses an outer surface of a lead body is adapted/means for passively preventing clots on a lead body includes forming a lead body such that a pseudo-intimal layer is formed on an outer surface when exposed to a bloodstream (column 1, lines 11–25, 27–35, 41–47; column 2, lines 24–27 and 49–51). Vachon does not disclose an outer surface of an electrode includes a textured coating including titanium microspheres (claims 1 and 17). However, Helland discloses an outer surface of an electrode includes a textured coating including titanium microspheres (column 3, lines 31–33; column 5, lines 46–49 and 51; column 6, lines 36–38; column 10, lines 30–32) to provide an implantable material having improved biocompatibility arriving from enhanced endothelial cell attachment properties (column 1, lines 24–27) and to increase electrical efficiency.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include an outer surface of a lead body is adapted such that a pseudo-intimal layer is formed on an outer surface when exposed to a bloodstream, as taught by McAuslan and an outer surface of an electrode includes a textured coating including titanium microspheres, as taught by Helland to provide an implantable material having improved biocompatibility arriving from enhanced endothelial cell attachment properties and to increase electrical efficiency.

Vachon discloses an outer surface of a lead does not include any active coatings which elute from the surface to minimize clotting (claim 9) (Figs. 1–2; column 5, lines 28–31 with the materials being those listed in column 4, lines 16–20); is coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy (claim 10) (column 5, line 12; column 1, lines 15–29; column 3, lines 43–46 and 56–60); an electrode includes a tip electrode (claim 24) (Fig. 1, element 20). Vachon and McAuslan do not disclose titanium microspheres have a diameter of between 75–100 μm (claim 5) and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (claims 7 and 18). However, Helland discloses titanium microspheres have a diameter of between 75–100 μm and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (column 3, lines 31–33; column 5, lines 46–49 and 51; column 6, lines 36–38; column 10, lines 3, 30–32 and 19–20) to increase the active surface area and enhance electrical efficiency (column 3, lines 26–27) and to provide superior pacing performance (column 8, lines 63–65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Vachon and McAuslan to include titanium microspheres have a diameter of between 75–100 μm and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface, as taught by Helland to increase the active surface area and enhance electrical efficiency and to provide superior pacing performance.

In the alternative for titanium microspheres, see the 35 U.S.C. 103(a) rejection below for claims 7 and 18.

5. Claims 11–16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mar et al., U.S. Patent 5,411,544 and in view of McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572.

Regarding claim 11, Mar discloses a lead body extending from a proximal end to a distal end, an electrode coupled to a lead body (Fig. 1), a lead body has a textured outer surface adapted to (column 4, lines 36–38). Mar does not disclose adapted to form a pseudo-intimal layer on an outer surface when exposed to a bloodstream so as to passively prevent formation of clots on an outer surface. However, McAuslan discloses adapted to form a pseudo-intimal layer on an outer surface when exposed to a bloodstream so as to passively prevent formation of clots on an outer surface (column 1, lines 11–25, 27–35, 41–47; column 2, lines 24–27 and 49–51). Mar does not disclose an electrode includes an outer textured surface including titanium microspheres. However, Helland discloses an electrode includes an outer textured surface including titanium microspheres (column 3, lines 31–33; column 5, lines 46–49 and 51; column 6, lines 36–38; column 10, lines 30–32) to provide an implantable material having improved biocompatibility arriving from enhanced endothelial cell attachment properties (column 1, lines 24–27) and to increase electrical efficiency.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include an outer surface of a lead body is adapted such that a pseudo-intimal layer is formed on an outer surface when exposed to a bloodstream, as taught by McAuslan and an outer surface of an electrode includes a textured coating including titanium microspheres, as taught by Helland to provide an implantable material

having improved biocompatibility arriving from enhanced endothelial cell attachment properties and to increase electrical efficiency.

Vachon discloses an outer surface of a lead does not include any active coatings which elute from a surface to minimize clotting (claim 14) (column 3, lines 42–54); a lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy (claim 16) (column 1, lines 8–10).

Neither Vachon nor McAuslan discloses an electrode outer surface adapted to trap blood cells within a textured surface to form a layer of blood cells on an electrode surface (claim 12) and titanium microspheres have a diameter of between 75–100 μm (claim 13) and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (claim 15). However, Helland discloses an electrode outer surface adapted to trap blood cells within a textured surface to form a layer of blood cells on an electrode surface (Figs 3 and 4) and titanium microspheres have a diameter of between 75–100 μm (column 3, lines 31–33; column 5, lines 46–49 and 51; column 6, lines 36–38; column 10, lines 3, 30–32, and 19–20) and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (column 6, lines 5–17) to increase the active surface area and enhance electrical efficiency (column 3, lines 26–27) and to provide interstitial porosity for tissue ingrowth (column 10, lines 34–35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Mar and McAuslan to include an electrode outer surface adapted to trap blood cells within a textured surface to form a layer of blood cells on an electrode surface and titanium microspheres have a diameter of between 75–

100 μm and titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface, as taught by Helland to increase the active surface area and enhance electrical efficiency and to provide interstitial porosity for tissue ingrowth.

In the alternative for microspheres, see the 35 U.S.C. 103(a) rejection below for claim 15.

6. In the alternative, claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon, U.S. Patent 5,861,023 and McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572 as applied to claims 1 and 17 above, and further in view of MacGregor, U.S. Patent 4,936,317.

Vachon does not disclose titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface. However, MacGregor discloses titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (column 1, lines 57–60; column 2, lines 61–67; column 3, lines 33, 58–60; column 5, lines 32–33) rendering the surface non-thrombogenic and resistant to the formation of blood clots (column 2, lines 67–68; column 1, lines 60–61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Vachon, McAuslan, and Helland to include titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface, as taught by MacGregor rendering the surface

non-thrombogenic and resistant to the formation of blood clots (column 2, lines 67–68; column 1, lines 60–61).

7. In the alternative, claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mar et al., U.S. Patent 5,411,544 and McAuslan, U.S. Patent 4,836,884 and Helland et al., U.S. Patent 5,318,572, as applied to claim 11 above, and further in view of MacGregor, U.S. Patent 4,936,317.

Mar does not disclose titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface. However, MacGregor discloses titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface (column 1, lines 57–60; column 2, lines 61–67; column 3, lines 33, 58–60; column 5, lines 32–33) rendering the surface non-thrombogenic and resistant to the formation of blood clots (column 2, lines 67–68; column 1, lines 60–61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Mar, McAuslan, and Helland to include titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface, as taught by MacGregor rendering the surface non-thrombogenic and resistant to the formation of blood clots (column 2, lines 67–68; column 1, lines 60–61).

Response to Arguments

8. Applicant's arguments with respect to claims 1, 11, and 17 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. Additionally, because claims 7, 18, and 15 depend from the amended corresponding parent claims, Applicants arguments have likewise been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

9. As a matter of record, Examiner uses the Helland et al. reference to read on the electrode limitation in the claimed invention, not the lead body outer surface as argued by the Applicant. Further, in response to Applicant's argument that there is no motivation to combine the Helland et al. and Vachon et al. references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. However, there is not requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
February 27, 2006
27 February 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/27/06